

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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NALOX-1 PHARMACEUTICALS, LLC,  
Petitioner,  
v.

ADAPT PHARMA OPERATIONS LIMITED, AND  
OPIANT PHARMACEUTICALS, INC.  
Patent Owners.

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CASE IPR2019-00688  
U.S. Patent No. 9,468,747

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**PETITIONER NALOX-1 PHARMACEUTICALS, LLC'S  
UPDATED EXHIBIT LIST**

**TABLE OF EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
<b>Nalox1001</b>	U.S. Patent No. 9,468,747 (the '747 patent)
<b>Nalox1002</b>	Expert Declaration of Maureen Donovan
<b>Nalox1003</b>	Expert Declaration of Günther Hochhaus
<b>Nalox1004</b>	Excerpt of File History of U.S. Patent No. 9,561,177, Aug. 22, 2016 Office Action, Non-Final Rejection (Aug. 22, 2016 Non-Final Rejection)
<b>Nalox1005</b>	Excerpt of File History of U.S. Patent No. 9,561,177, Oct. 21, 2016 Amendment and Response to Office Action (Oct. 21, 2016 Response to Office Action)
<b>Nalox1006</b>	Excerpt of File History of U.S. Patent No. 9,561,177, Dec. 21, 2016 Office Action, Notice of Allowance and Fees Due (Notice of Allowance)
<b>Nalox1007</b>	U.S. Patent No. 9,192,570 (Wyse)
<b>Nalox1008</b>	Chinese Patent No. 1,575,795 (Wang)
<b>Nalox1009</b>	PCT International App. Pub. No. WO00/62757 (Davies)
<b>Nalox1010</b>	Djupesland, P., <i>Nasal Drug Delivery Device: Characteristics and Performance in a Clinical Perspective - A Review</i> , 3 Drug Deliv. & Transl. Res. 42–62 (2013) (Djupesland)
<b>Nalox1011</b>	Grassin-Delyle, S. et al., <i>Intranasal Drug Delivery: An Efficient and Non-invasive Route for Systemic Administration, Focus on Opioids</i> , 134 Pharm. & Ther. 366–79 (2012) (Grassin-Delyle)
<b>Nalox1012</b>	Handbook of Pharmaceutical Excipients, 56–60, 64–66, 78–81, 220–22, 242–44, 270–72, 441–45, 517–22, 596–98 (Rowe, R. et al. eds., 6th ed. 2009) (HPE)
<b>Nalox1013</b>	Kushwaha, S. et al., <i>Advances in Nasal Trans-Mucosal Drug Delivery</i> , (1)7 J. Applied Pharm. Sci. 21–28 (2011) (Kushwaha)
<b>Nalox1014</b>	U.S. Patent No. 5,866,154 (Bahal)
<b>Nalox1015</b>	U.S. Patent No. 8,198,291 (the '291 patent)

<b>Exhibit Number</b>	<b>Description</b>
<b>Nalox1016</b>	Wermeling, D., <i>A Response to the Opioid Overdose Epidemic: Naloxone Nasal Spray</i> , 3 Drug Deliv. & Transl. Res. 63–74 (2013) (Wermeling 2013)
<b>Nalox1017</b>	Alabama Department of Public Health, <i>Alabama EMS Patient Care Protocols</i> (7th ed., Oct. 2013) (Alabama EMS Protocols)
<b>Nalox1018</b>	Aptar Pharma, Press Release, Aptar Pharma Provides Unit-Dose Nasal Spray Technology for Treatment of Opioid Overdose (Apr. 20, 2016) (Aptar Press Release)
<b>Nalox1019</b>	Ashton, H. et al., <i>Best Evidence Topic Report Intranasal Naloxone in Suspected Opioid Overdose</i> , 23(3) Emerg. Med. J. 221–23 (2006) (Ashton)
<b>Nalox1020</b>	Barton, E. et al., <i>Intranasal Administration of Naloxone by Paramedics</i> , 6 Prehosp. Em. Care 54–58 (Barton 2002)
<b>Nalox1021</b>	Barton, E. et al., <i>Efficacy of Intranasal Naloxone as a Needleless Alternative for Treatment of Opioid Overdose in the Prehospital Setting</i> , 29(3) J. Emerg. Med. 265–71 (2005) (Barton 2005)
<b>Nalox1022</b>	Bitter, C. et al., <i>Nasal Drug Delivery in Humans</i> , 40 Curr. Probl. Dermatol. 20–35 (2011) (Bitter)
<b>Nalox1023</b>	Boyer, E., <i>Management of Opioid Analgesic Overdose</i> , 367(2) N. Engl. J. Med. 146–55 (2012) (Boyer)
<b>Nalox1024</b>	CDC, NDA No. 21-450 Clinical Pharmacology & Biopharmaceutics Review (2002) (Zomig Review)
<b>Nalox1025</b>	Excerpt of Commonwealth of Kentucky, <i>Kentucky Patient Care Protocols</i> (Mar. 13, 2015) (Kentucky Patient Care Protocols)
<b>Nalox1026</b>	Costantino, H. et al., <i>Intranasal Delivery: Physiochemical and Therapeutic Aspects</i> , 337 Int'l. J. of Pharm. 1–24 (2007) (Constantino)
<b>Nalox1027</b>	Dowling, J. et al., <i>Population Pharmacokinetics of Intravenous, Intramuscular, and Intranasal Naloxone in Human Volunteers</i> , 30(4) Ther. Drug. Monit. 490–96 (2008) (Dowling)
<b>Nalox1028</b>	FDA, Center for Drug Evaluation and Research, Guidance for Industry, <i>Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products – Chemistry, Manufacturing, and Controls Documentation</i> (2002) (2002 FDA Guidance)

<b>Exhibit Number</b>	<b>Description</b>
<b>Nalox1029</b>	FDA, Center for Drug Evaluation and Research, Guidance for Industry, <i>Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action</i> (2003) (2003 FDA Guidance)
<b>Nalox1030</b>	Freise, K. et al., <i>Naloxone Reversal of an Overdose of a Novel, Long-Acting Transdermal Fentanyl Solution in Laboratory Beagles</i> , 35(2) J. Vet. Pharmacol. Therap. 45–51 (2012) (Freise)
<b>Nalox1031</b>	Glende, O., <i>Development of non-injectable naloxone for pre-hospital reversal of opioid overdose: A Norwegian project and a review of international status</i> (May 2016) (unpublished M.A. thesis, Norwegian University of Science and Technology) (on file with Norwegian University of Science and Technology) (Glende)
<b>Nalox1032</b>	Hertz, S., <i>Naloxone for Outpatient Use: Data Required to Support an NDA</i> , PowerPoint Presentation (Hertz Presentation)
<b>Nalox1033</b>	Intentionally left blank
<b>Nalox1034</b>	Kelly, A-M. et al., <i>Randomised Trial of Intranasal Versus Intramuscular Naloxone in Prehospital Treatment for Suspected Opioid Overdose</i> , 182(1) Med. J. Austl. 24–27 (2005) (Kelly)
<b>Nalox1035</b>	Kerr, D. et al., <i>Intranasal Naloxone for the Treatment of Suspected Heroin Overdose</i> , 103 Addiction 379–86 (2008) (Kerr 2008)
<b>Nalox1036</b>	Kerr, D. et al., <i>Randomized Controlled Trial Comparing the Effectiveness &amp; Safety of Intranasal &amp; Intramuscular Naloxone for the Treatment of Suspected Heroin Overdose</i> , 104 Addiction 2067–74 (2009) (Kerr 2009)
<b>Nalox1037</b>	Kleiman-Wexler, R. et al., <i>Pharmacokinetics of Naloxone-An Insight into the Locus of Effect on Stress-Ulceration</i> , 251(2) J. Pharmacol. Exp. Ther. 435–38 (1989) (Kleiman-Wexler)
<b>Nalox1038</b>	Marple, B. et al., <i>Safety Review of Benzalkonium Chloride Used as a Preservative in Intranasal Solutions: An Overview of Conflicting Data and Opinions</i> , 130 Otolaryngol Head Neck Surg. 131–41 (2004) (Marple)
<b>Nalox1039</b>	Merck Index, <i>Isotonic Solutions</i> , MISC-47–69 (Windholz, M. et al. eds., 10th ed. 1983) (Merck Index)

**IPR2019-00688 – U.S. Patent No. 9,468,747**  
**Updated Exhibit List**

<b>Exhibit Number</b>	<b>Description</b>
<b>Nalox1040</b>	Merlin, M. et al., <i>Intranasal Naloxone Delivery is an Alternative to Intravenous Naloxone for Opioid Overdoses</i> , 28 Am. J. Emerg. Med. 296–303 (2010) (Merlin)
<b>Nalox1041</b>	Middleton, L. et al., <i>The Pharmacodynamic &amp; Pharmacokinetic Profile of Intranasal Crushed Buprenorphine &amp; Buprenorphine/Naloxone Tablets in Opioid Abusers</i> , 106(8) Addiction 1460–73 (2011) (Middleton)
<b>Nalox1042</b>	Monitto, C. et al., <i>The Optimal Dose of Prophylactic Intravenous Naloxone in Ameliorating Opioid-Induced Side Effects in Children Receiving Intravenous Patient-Controlled Analgesia Morphine for Moderate to Severe Pain: A Dose Finding Study</i> , 113(4) Anesthesia & Analgesia 834–42 (2011) (Monitto)
<b>Nalox1043</b>	<i>Pharmacodynamic Agents</i> , in Foye's Principles of Medicinal Chemistry, 670 (Lemke, T. et al. eds., 6th ed. 2008) (Lemke)
<b>Nalox1044</b>	Physicians' Desk Reference, <i>NARCAN [Naloxone Hydrochloride Injection, USP]</i> , <i>IMITREX Nasal Spray [Sumatriptan]</i> , 1300–02, 1546–50 (57th ed., 2003) (PDR 2003)
<b>Nalox1045</b>	Physicians' Desk Reference, <i>ZOMIG Nasal Spray [Zolmitriptan]</i> , 768–78 (64th ed., 2010) (PDR 2010)
<b>Nalox1046</b>	Robertson, T. et al., <i>Intranasal Versus Intravenous Naloxone for Prehospital Narcotic Overdose</i> , Abstract, 12(5)(1) Acad. Emerg. Med. 166–67 (2005) (Robertson 2005)
<b>Nalox1047</b>	Robertson, T. et al., <i>Intranasal Naloxone is a Viable Alternative to Intravenous Naloxone for Prehospital Narcotic Overdose</i> , 13 Prehosp. Emerg. Care 512–15 (2009) (Robertson 2009)
<b>Nalox1048</b>	<i>Role of Naloxone in Opioid Overdose Fatality Prevention; Public Workshop; Request for Comments</i> , 76 Fed. Reg. 71,348 (Nov. 17, 2011) (Role of Naloxone Fed. Reg. Notice)
<b>Nalox1049</b>	<i>Role of Naloxone in Opioid Overdose Fatality Prevention</i> FDA Meeting Transcript (Apr. 12, 2012) (2012 FDA Meeting)
<b>Nalox1050</b>	Rosanske, T., <i>Morphine</i> , in Chemical Stability of Pharmaceuticals: A Handbook for Pharmacists, 604–11 (Connors, K. et al. eds., 2d ed. 1986) (Rosanske)
<b>Nalox1051</b>	Sabzghabae, A. et al., <i>Naloxone Therapy in Opioid Overdose Patients: Intranasal or Intravenous? A Randomized Clinical Trial</i> , 10(2) Arch. Med. Sci. 309–14 (2014) (Sabzghabae)

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